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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,421	09/26/2000	Dale Wallis	40224.00001	5703

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EXAMINER
NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/670,421	Wallis et al
Examiner	**Art Unit**
Mark Navarro	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 12-19 is/are pending in the application.

4a) Of the above, claim(s) 12-17 and 19 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 18 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's response filed July 30, 2002, (Paper Number 10) has been received and entered. Consequently claims 12-19 are pending in the instant application, of which claims 12-17 and 19 have been withdrawn from further consideration as being drawn to a non-elected invention in Paper Number 6, received January 22, 2002.

Claim Rejections - 35 USC § 112

1. The rejection of claim 18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition of Serpens strain HBL-112, does not reasonably provide enablement for all pharmaceutical compositions of Serpens, immunologically active portions thereof, and antigenic epitopes cross-reactive with the Serpens genera is maintained.

Applicant's are asserting that "it is not necessarily a requirement that a vaccine elicit a protective immunity, but merely to induce a resistance to microorganisms." Applicant's further assert that opsonization is a process involving neutralization, and that by inference any single antibody which binds to the microorganism - and by extension any binding monoclonal antibody population raised against a single epitope - serves to enhance resistance to that microorganism. Applicant's further assert that the Examiner's reference to a "single protein" does not address the entire scope of this application. Applicant's further assert that the Examiner's reliance upon a protein-based epitope argument is questionable given that the more likely target is polysaccharide.

Applicant's further assert that Fox was filed in 1986, and that Wisdom et al (1994) updates these teachings by setting forth that "relatively short, linear peptides can often induce useful cross-reactive antibodies." Applicant's finally assert that because the epitope definition by an antibody is an extremely precise one, it therefore meets the requirements of the court for a "precise definition" by structure and physical property, and that a person of ordinary skill in the art would recognize that applicant has invented what is claimed.

Applicant's arguments have been fully considered but are not found to be fully persuasive.

First, Applicant's assert that it is not necessarily a requirement that a vaccine elicit a protective immunity, but merely to induce a resistance to microorganisms." However, a vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Accordingly, Applicant's are enabled for "immunogenic compositions" but not vaccine or pharmaceutical compositions.

Likewise, Applicant's assertions that a single antibody enhances resistance to that microorganism are also addressed by In re Wright.

Applicant's further assert that the Examiner's reference to a "single protein" does not address the entire scope of this application. However, Applicant's are respectfully directed to the claim language. Claim 18 recites "immunologically active portions and an antigenic epitope cross-reactive with the Serpens genera in combination with a veterinarily acceptable diluent or a

carrier." Clearly immunologically active portions and/or antigenic epitopes include single proteins, and the teachings of Ellis and Fox are clearly applicable to the claim language.

Applicant's further assert that Fox was filed in 1986, and that Wisdom et al (1994) updates these teachings by setting forth that "relatively short, linear peptides can often induce useful cross-reactive antibodies." However, again as set forth in In re Wright, mere generation of antibodies is not the issue, the question that remains is are the ensuing antibodies capable of providing immunoprotection?

Finally, Applicant's assert that because the epitope definition by an antibody is an extremely precise one, it therefore meets the requirements of the court for a "precise definition" by structure and physical property, and that a person of ordinary skill in the art would recognize that applicant has invented what is claimed. However, Applicant's appear to be defining an antibody to an undefined protein. Which protein or proteins of Serpens, as claimed by immunologically active portions and cross-reactive epitopes, are the ones eliciting immunoprotective antibodies? Applicant's have not described the structure or function of any of these proteins, consequently, those of skill in the art would not be able to recognize that applicant has invented what is claimed.

The claims are directed to pharmaceutical compositions for the prevention and treatment of Papillomatous Digital Dermatitis in ruminants comprising a therapeutically effective amount of at least one member selected from the group consisting of bacterial species belonging to the genus

Serpens; an immunologically active portion thereof; and an antigenic epitope cross-reactive with the Serpens genera in combination with a veterinarily acceptable diluent or a carrier.

It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A *et al.*,(ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen." Fox (U.S. Patent Number 4,879,213) sets forth that "without knowing a protein's three dimensional structure there is no reliable method for determining which linear segments of the protein are accessible to the host's immune system" and that "whether the three dimensional structure is known or not, short linear polypeptides often appear not to have the ability to mimic the required secondary and tertiary conformational structures to constitute appropriate immunogenic and antigenic determinants." Consequently determining immunologically active portions or antigenic epitopes cross-reactive with the Serpens genera is unpredictable and would require undue experimentation as evidenced by Plotkin *et al* and Fox *et al.*

Furthermore, *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written

description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116). Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Thus, Applicant's have not provided sufficient guidance to enable one skilled in the art to make and use the claimed immunologically active portion thereof, or an antigenic epitope cross-reactive with the Serpens genera in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made

is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986).

For reasons of record in Paper Number 7, as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The rejection of claim 18 under 35 U.S.C. 102(b) as being anticipated by Hespell is maintained.

Applicant's are asserting that Hespell never intended to formulate Serpens bacteria as a pharmaceutical composition. Applicant's further assert that the disclosure of Hespell culturing the Serpens flexibilis in a lactate broth which contained distilled water cannot be seen to anticipate a pharmaceutical composition since none of the other ingredients were of pharmaceutical quality or functionality and thereby contaminate and are unacceptable for use in a pharmaceutical

composition. Finally Applicant's assert that distilled water *per se* is simply not an acceptable pharmaceutical component, and thus could not be acceptable as an ingredient in a pharmaceutical composition.

Applicant's arguments have been fully considered but are not found to be fully persuasive.

Applicant's arguments are not found to be fully persuasive in view of the disclosure of Hespell.

First, the intentions of Hespell are wholly irrelevant, the claims are drawn to a composition, as long as each and every limitation of the composition is disclosed the reference is deemed anticipatory.

Second, Applicant's assert that since the lactate broth contained other ingredients which were not of pharmaceutical quality. However Applicant's have not identified any components in the lactate broth, other than distilled water, which would be prohibited in a pharmaceutical carrier. Furthermore, Applicant's specifically point out this one ingredient, distilled water, and assert that it is simply not acceptable in a pharmaceutical composition. However, Applicant's attention is respectfully directed to U.S. Patent Number 3,607,909, column 2, lines 50-52, which sets forth that the compounds of the instant invention may be administered to patients with the "usual pharmaceutical solid or liquid carriers such, for example, as distilled water,..." Applicant's assertions that distilled water is not an acceptable pharmaceutical acceptable carrier are clearly and directly contradicted by the teachings of U.S. Patent Number 3,607,909.

The claims are directed to pharmaceutical compositions for the prevention and treatment of Papillomatous Digital Dermatitis in ruminants comprising a therapeutically effective amount of at least one member selected from the group consisting of bacterial species belonging to the genus Serpens; an immunologically active portion thereof; and an antigenic epitope cross-reactive with the Serpens genera in combination with a veterinarily acceptable diluent or a carrier.

Hespell (International Journal of Systematic Bacteriology, Vol. 27, No. 4, pp 371-381, October 1977) disclose of isolated *Serpens flexibilis*. Hespell further discloses of culturing *Serpens flexibilis* in a lactate broth which contains 100 ml of distilled water.

In view that Hespell discloses of an isolated *Serpens flexibilis* in combination with a veterinarally acceptable diluent (distilled water), the disclosure of Hespell is seen to anticipate the claimed invention.

It is noted that Hespell does not set forth that the composition is used for the prevention and treatment of Papillomatous Digital Dermatitis in ruminants, however such a recitation is an intended use of the claimed composition, and therefore, carries no weight when compared to the disclosure of Hespell.

For reasons of record in Paper Number 7, as well as the reasons set forth above, this rejection is maintained.

Double Patenting

3. The rejection of claim 18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,162,429 is maintained.

It is noted that Applicant's have indicated a willingness to file a terminal disclaimer upon the indication of allowable subject matter, however until a terminal disclaimer is made of record this rejection is maintained for reasons of record in Paper Number 7.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner

can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

October 30, 2002